



Bioterrorism and Health System Preparedness



Addressing the Smallpox Threat: Issues, Strategies, and Tools



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The Agency for Healthcare Research and Quality (AHRQ) is the lead agency charged with supporting research designed to improve the quality of health care, reduce its cost, address patient safety and medical errors, and broaden access to essential services. AHRQ sponsors and conducts research that provides evidence-based information on health care outcomes; quality; and cost, use, and access.

The information helps health care decisionmakers—patients and clinicians, health system leaders, and policymakers—make more informed decisions and improve the quality of health care services.



U.S. Department of Health
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Public Health Service

Introduction

A bioterrorist attack using smallpox would pose a significant threat to public health in the United States. The reintroduction of the smallpox virus—which has not infected anyone in the world for nearly three decades—into an unprotected population could cause substantial morbidity and mortality and overwhelm public health resources. While the threat of such an attack is of national concern, it is at the local level that public health officials and health system planners must be ready to respond.

On March 3, 2003, an audioconference sponsored by the Agency for Healthcare Research and Quality (AHRQ) examined the implementation of the Centers for Disease Control and Prevention's (CDC's) smallpox vaccination program and strategies to assist public health officials in responding to a potential smallpox outbreak. Panelists included:

- s Nancy Ridley, Assistant Commissioner, Massachusetts Department of Public Health;
- s Edward Gabriel, Deputy Commissioner for Preparedness, New York City Office of Emergency Management;
- s Nathaniel Hupert, M.D., Weill Medical College of Cornell University; and
- s Thomas Terndrup, M.D., Director, Center for Disaster Preparedness, University of Alabama at Birmingham.

Following presentations by the panelists, listeners were invited to submit questions during a question and answer period.

This issue brief reviews vaccination efforts and identifies tools to help hospital administrators and emergency responders prepare for an outbreak of smallpox and other deadly diseases that can be caused by biological or chemical attacks.

The Smallpox Threat

The last case of smallpox in the United States occurred in 1949. The last natural case documented in the world occurred in Somalia in 1977. In this country, vaccination against smallpox stopped in

- s William Raub, Ph.D., Deputy Assistant Secretary, Office of Public Health Emergency Preparedness, U.S. Department of Health and Human Services;



1972 and, in 1980, the World Health Organization declared that the disease had been globally eradicated. Although there is no reason to believe that smallpox presents an imminent threat today, the terrorist attacks of September 11, 2001, and the anthrax attacks that followed them have heightened concern that terrorists may have obtained the virus and will attempt to use it against the American public.

Smallpox is one of six biological agents that the CDC views as a high-priority threat because of the effects of the disease and its potential for large-scale dispersal.¹ William Raub listed five reasons why smallpox is considered a threat:

- s It is highly lethal; without vaccination, 30 percent of those infected can expect to die, and of those who survive there can be lifelong, serious morbidities of various types;
- s The disease is readily communicable from person to person; respiratory droplets are sufficient to carry the virus, and therefore ordinary day-to-day contact can be sufficient exposure to spread the disease;
- s Few people have effective immunity; with vaccination having ended in the United States in the 1970s, individuals born since that time have no immunity and those of us who were vaccinated earlier have little or none, depending on the length of time involved;
- s We have no established treatment; the vaccine itself is protective within a few days of exposure, but

once the symptoms present we have no drugs or other means to treat, much less cure, this disease; and

- s Enemies of the United States may obtain the variola virus, which causes smallpox.

After eradication of the disease in 1980, only two official stockpiles of variola virus remain—one in the United States and the other in the Soviet Union. Much of the former Soviet Union's supply is still not accounted for today. "When scientists and engineers left that country following the breakup of the former Soviet Union, we fear that they left with more than their know-how," said Dr. Raub. "They may indeed have left with samples of the virus."

Smallpox Preparedness Efforts

President Bush announced the Smallpox Vaccination Program in December 2002. In the first phase, the U.S. Department of Health and Human Services was to work with state and local governments to form volunteer Smallpox Response Teams, composed of health care workers and emergency response personnel, who would receive a "pre-event" inoculation. The response teams would thus be protected against smallpox and would be ready to mobilize immediately in a smallpox emergency to vaccinate others. The first phase also included vaccination of military personnel who were or might be deployed in a high-threat area, and voluntary vaccination of State Department personnel assigned to such areas.

William Raub stressed that the

program is voluntary. He went on to explain that the plan included two other phases. Phase 2 would include the voluntary vaccination of additional members of the health care and public safety communities who, in the event of an outbreak of smallpox, would be among the very first to be exposed to cases and who would want to be protected to be able to carry out their basic responsibilities. In the third phase, voluntary vaccination would be available to members of the general public who, in the President's words, "insist on being vaccinated now."

"First, I would stress that the program is entirely voluntary. Smallpox does not exist in the world right now; we believe it would be inappropriate to have any mandatory vaccination campaign for a disease that does not exist. But because of the bioterrorist threats, some preparation seems important."

William Raub, Deputy Assistant Secretary for Public Health Emergency Preparedness

After the President's announcement, CDC promulgated guidance for the Smallpox Vaccination Program, made educational materials about smallpox and vaccination available to hospitals, clinicians, and the public, and provided smallpox vaccine to the States. The program was implemented in late

¹ The other agents are anthrax, botulism, plague, tularemia, and viral hemorrhagic fevers.



January 2003.

Vaccination Program Challenges

In the 5 weeks between the implementation of the program and the audioconference, not surprisingly, some issues arose. Dr. Raub identified two. The first was the logistics and cost anticipated for Phase 2 of the vaccination program. He explained that most States were able to handle the logistics and were finding funds for Phase 1 (for which CDC had targeted a total of 500,000 vaccinees). With up to 10 million additional health care workers and emergency response personnel projected to be vaccinated in Phase 2, however, some State and local health officials were apprehensive about the financial resources that would be needed to implement such a large-scale effort. On that scale, the distribution of vaccine, the types of clinics or other arrangements for vaccination, and access to those sites would also pose a major logistical challenge.

The second issue was the absence of guaranteed compensation for vaccine-related injuries. In many States, but not all, workman's compensation covers the compensation needed for illness resulting from the possible side effects of vaccination. Similarly, many health insurance programs, but not all, provide coverage for the health care costs associated with adverse events, but none of them covers the costs associated with lost work. As a result, State officials and hospitals and others were proceeding cautiously with the vaccination program in the hope that a solution to the compensation problem

would be found.

The Massachusetts Experience

Massachusetts offers an example of one State's efforts to implement the Smallpox Vaccination Program. As Nancy Ridley explained, the Massachusetts plan is built around its acute care system and its emergency response planning regions. Massachusetts does not operate on a county health system, but has 76 acute care hospitals with emergency rooms that make up the core of the acute care system. The State has recently been divided into seven emergency response planning regions so that each region

emergency response regions would have multiple 16-member response teams, which would require vaccinating approximately 150 community response team members per region. Completion of the two components of Phase 1 was expected to take up to 6 months.

The Massachusetts plan included several precautions. Volunteers had to have been vaccinated previously. There would also be very careful screening of the volunteers and their household contacts for contraindications. In addition, extensive followup would be required for adverse reactions. In light of those precautions, the State was not proposing or recommending furloughs.

"In terms of getting consumers and the public involved in the program, you need to have the continuous involvement of health care providers right from the beginning."

Nancy Ridley, Assistant Commissioner, Massachusetts
Department of Public Health

has an approximately equal population and number of hospitals.

The Massachusetts approach to Phase 1 started with planning by a statewide smallpox workgroup that included 40 or 50 active members representing many different constituent groups. Their Phase 1 plan had two components. First, State health department personnel would be vaccinated and would, in turn, vaccinate approximately 7,600 hospital staff, averaging about 100 per acute-care hospital. Second was the vaccination of community response team personnel. Each of the 7

With regard to Phase 2 of the Vaccination Program, Ms. Ridley added another dimension to the issues identified by William Raub. She described proceeding to Phase 2 as "one of the most controversial questions we have had to face," and stressed that moving to Phase 2 was dependent on the lessons learned during Phase 1. Specifically, she said that what was necessary to proceed to Phase 2 was continuation of evidence to date that the program had been very successful, with very small numbers of even minor adverse reactions.

The experience in Massachusetts with the compensation issue was that,



because worker's compensation in the State does not take effect until the fifth day, many larger employers had stated that they would cover those first days. Similarly, health insurers had said they would cover side effects for both vaccinees and any contacts.

Smallpox Threat Requires Coordination, Communication

Edward Gabriel, Deputy Commissioner for Preparedness in the New York City Office of Emergency Management, stressed that planning for a smallpox threat—or any public health emergency—must begin with communication and coordination among local emergency authorities. He described incident management planning as “a way to bring everybody to the table and get them to speak the same language.” “Everybody” includes not only hospitals and emergency medical services, but also local public health departments and fire, police, and ambulance personnel. In addition to “speaking the same language,” incident management planners should get to know one another on a first-name basis, face to face, and should consider each other as part of the same emergency response team.

Local planners should also work with State and Federal representatives. In response to a call-in question, Mr. Gabriel said that one of the lessons of 9/11 was the importance of coordination of emergency management at the local, State, and Federal levels. It is important to know who the contact points are and “where to go for what resources, how to get them, and how your chain works from

the lower level to the State level to the Federal level.”

An especially important element of that local-State-Federal coordination in the event of any public emergency is communication with the public. “Our experiences from September 11 taught us the importance of projecting one voice and a consistent message to the public,” said Gabriel. Nancy Ridley added that one of the highest priorities in making a smallpox plan successful is being prepared to counter “an epidemic of fear” among the public.

“Do your preparedness planning not just for bioterrorism incidents but for all incidents.”

Edward J. Gabriel, New York Office of Emergency Management

New Tools Help Prepare for Deadly Diseases

If a smallpox outbreak were to occur, a large-scale vaccination program would be necessary. Researchers at Weill Medical College of Cornell University have designed a new computer model to help hospitals and health systems plan antibiotic dispensing and vaccination campaigns to respond to bioterrorism or large-scale natural disease outbreaks. The model was funded by AHRQ and developed by researchers after testing a variety of patient triage and drug-dispensing plans.

Now, for the first time, hospital

planners can estimate the number and type of staff needed to vaccinate an entire community in an efficient and timely fashion. For example, the model can quantify the staff required to vaccinate one million people over 14 days. The model can be downloaded to run on common spreadsheet software customized for use by health officials at all levels of government, hospital administration, and emergency medical planning.

“Models like this allow planners to think with numbers when designing mass prophylactic response strategies,” said lead model designer Nathaniel Hupert of Weill Medical College. Modeling also forces a critical examination of assumptions about how a large-scale vaccination plan would be executed, particularly the issue of resource availability. Dr. Hupert cautioned that while “models are useful to guide planning, they don’t replace the real thing, which is exercises and drills that test the response of a health care system.”

Educating Providers About Bioterrorist Agents

Dr. Thomas Terndrup, Director of the Center for Disaster Preparedness at the University of Alabama at Birmingham, demonstrated the Web site (www.bioterrorism.uab.edu) that he and his colleagues have developed to provide resource information and continuing education about rare infections and potential bioterrorist agents, including anthrax and smallpox, to health care providers. The biggest challenge, he said, was that “there is limited or no clinical experience with many of these agents,



and so the health care community needs to struggle with recognition and awareness.”

Funded by AHRQ, the interactive screensaver on the Web site includes assistance with complicated differential diagnosis, continuing education modules, related Web links, and publications options for the user. The Web site was initially posted in October 2001 and has been updated regularly, especially for smallpox and anthrax. A pediatrics model was added in December 2002, and other modules were being planned, including internal medicine and family practice to incorporate primary care physicians into the fold. Also in the planning stage was a dermatology referral module that would help medical providers to know when to refer a patient to the dermatology community.

Update

Four weeks after the audioconference, on March 26, 2003, CDC issued an advisory that people with known cardiac disease should not be vaccinated. CDC's March 28, 2003, *Morbidity and Mortality Weekly Report* contained the news that seven cases of cardiac adverse events had been reported among the 25,645 civilians who had been vaccinated as of March 21, 2003, and that 10 cases of myopericarditis had been reported among approximately 225,000 primary vaccinees in the military smallpox vaccination program. In the military program, no cases of myocarditis or pericarditis had been reported among approximately 100,000 persons who had been revaccinated. CDC cautioned that a causal relation between smallpox vaccination and serious cardiac events

could not be excluded, and recommended that persons with known cardiac disease be excluded from vaccination.

Other notable events since the March 3, 2003 audioconference include the following:

March 31—CDC added a supplement on “Smallpox Vaccine and Heart Problems” to its Smallpox Pre-Vaccination Information Packet.

April 30—President Bush signed into law the Smallpox Emergency Personnel Protection Act of 2003 (SEPPA) (P.L. 108-20). The law established a no-fault program to provide benefits or compensation to health care workers and emergency responders who are injured as the result of the administration of smallpox countermeasures, including the smallpox vaccine.

May 5—HHS Secretary Thompson announced the release of \$100 million to the States to help them prepare for a possible smallpox attack and to strengthen the public health infrastructure. The \$100 million was in addition to the \$1.4 billion available to the States in Fiscal Year 2003.

May 23—The Institute of Medicine's (IOM) Committee on Smallpox Vaccination Program Implementation issued its Letter Report #3 to CDC, reaffirming the recommendation from its first Letter Report (January 16, 2003) that there should be a pause in the program between Phase 1 and Phase 2. The IOM May report cited three reasons for the pause: to ensure that expanded vaccination is as safe as possible for vaccinees and their contacts; to modify plans, data systems,

and educational materials to prepare for a new population of potential vaccinees; and to re-evaluate the vaccination program's integration into overall smallpox preparedness nationally and locally.

June 18—The Advisory Committee on Immunization Practices (ACIP) issued a Statement on Smallpox Preparedness and Vaccination in which it reiterates that it is critical that smallpox preparedness planning continue at all levels of government. The statement provides a list of preparedness efforts and activities, including smallpox vaccination. It also advises CDC not to expand beyond ACIP's current, pre-event smallpox vaccination recommendations, specifically because the extent and severity of myopericarditis are not yet known.

November 6—In its weekly update of Smallpox Vaccination Program Status by State, CDC reported that as of October 31, 2003, a total of 38,759 civilians nationwide had received the smallpox vaccination.

For More Information

The complete audioconference on “Addressing the Smallpox Threat: Issues, Strategies and Tools” is available as a streaming presentation and as a text transcript on the AHRQ Web site (www.ahrq.gov/bioterbr.htm).

Information on the tools discussed in this issue brief, and other tools and publications related to health system preparedness for bioterrorism, will be posted on the AHRQ Web site as it becomes available. Please check the Web site frequently.



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